FDA 510(k) Premarket Notification

# K221794 Vario-Cup System

**CLEARED**

Jul 20, 2022
29 days to decision

K221794 · Product code: **KWY** · Orthopedic
Source: https://www.510kdatabase.net/k221794/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY) |
| Date received | Jun 21, 2022 |
| Decision date | Jul 20, 2022 |
| Days to decision | 29 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Waldemar Link GmbH & Co. KG** |
| Location | Mchenry, IL, US |
| Contact | Pia Mueller |
| 510(k) history | 42 submissions · 42 cleared · 1978-2025 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **LinkBio Corp.** |
| Contact | Mateusz Leszczak |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov